

Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University
SESSION: Interoperability SIG Breakout

Session Information	Date: May 31, 2007 Time: 9:50 a.m. – 10:45 a.m. PDT Presenter/Lead: Peter Covitz (Smita Hastak, BRIDG; Patrick McConnell, CTMSi) Facilitator: Mark Adams Scribe: Karen Ryan								
Executive Summary	The Interoperability SIG is concerned with the integration of the Structured Protocol Representation (Biomedical Research Integrated Domain Group [BRIDG]) project and the Clinical Trials Interoperability Project, and the System Interoperability and Harmonization efforts.								
Discussion	<p>CTWG System Interoperability and Harmonization (SIH) SIG</p> <ul style="list-style-type: none">BRIDG project—The official Release 1.0 is due June 15, 2007 (status and process presented by Smita Hastak). Release 1.0 includes scope from the five project static models of the four stakeholders (National Cancer Institute [NCI] Patient Study Calendar [PSC], NCI Lab Domain, 50 percent of Clinical Trials Object Model [CTOM], Clinical Data Interchange Standards Consortium [CDISC] Study Data Tabulation Model [SDTM], and HL7 Regulated Project Submission). Annual releases are to follow, tying in projects, with dot releases each quarter. Downloads will be available on gForge. Comments and feedback on the model are sought—it is important for community members to review the model and communicate any issues, what may be missing, etc. Primary focus of the BRIDG project is the semantics.Clinical Trials Management System Interoperability (CTMSi) project—Coordination activity is ongoing, and a demo prototype available. An Architecture Overview was presented by Patrick McConnell. Project is leveraging and extending phase 1 work, developing clinical trials workflow use cases. BRIDG was leveraged heavily in development.Discussion on the requirements gathering for clinical trial data sharing did not involve review of the projects against the DSIC matrix as was performed in other breakouts. Data sensitivity for SIH is inherited from component systems, and data sensitivity for BRIDG is inherited from the trials represented.The Interoperability task force will communicate directly with the others (Planning/Monitoring, Conduct, Reporting/Sharing). The Interoperability task force will provide resources for the enterprise SIG framework. <p>SIG calls will be conducted; Booz Allen Hamilton is responsible for coordinating.</p>								
Requirements	<table><tr><th>Req. #</th><th>Name</th><th>Description</th></tr><tr><td></td><td></td><td></td></tr></table>			Req. #	Name	Description			
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Issues	<table><tr><th>Issue ID</th><th>Description</th></tr><tr><td>1</td><td>There is a need for a protocol abstraction system. There was general agreement. The possibility was raised that this could conceivably be switched</td></tr></table>			Issue ID	Description	1	There is a need for a protocol abstraction system. There was general agreement. The possibility was raised that this could conceivably be switched		
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1	There is a need for a protocol abstraction system. There was general agreement. The possibility was raised that this could conceivably be switched								

		to be part of the Planning/Monitoring task force, whether developed from scratch or taking advantage of something else already available. It was agreed that the latter was preferable.		
	2	Regarding BRIDG, the question was raised regarding how information vetted by the developers is communicated to the BRIDG modelers. The process for doing so is very use case driven; the elements are taken as a use case that needs to be harmonized with the BRIDG model. The BRIDG Advisory Board meets to determine the priority of the projects to harmonize. The BRIDG Technical Harmonization Committee meets in person to harmonize a model every month (over the course of 3 days each month).		
Action Items				
	Assigned To	Description		Due Date
Attendance	#	First Name	Last Name	Affiliation
	1.	Christo	Andonyadis	NCI CBIIT
	2.	Rhoda	Arzoomanian	Univ. of Wisconsin-Madison
	3.	Laura	Bradley	OHSU
	4.	Amar	Chahal	Velos
	5.	Deborah	Collyar	PAIR
	6.	Don	Connelly	Univ. of Minnesota
	7.	Paul	Courtney	Dartmouth College
	8.	Peter	Covitz	NCI CBIIT
	9.	Mary Jo	Deering	NCI CBIIT
	10.	Leslie	Derr	NCI CBIIT
	11.	Sharon	Elcombe	Mayo Clinic
	12.	Doug	Fridsma	UPMC
	13.	Steve	Friedman	CTEP
	14.	Meg	Gronvall	Booz Allen Hamilton
	15.	Smita	Hastak	ScenPro
	16.	Julie	Holtzople	Booz Allen Hamilton
	17.	Bob	Lanese	Case
	18.	Jack	London	Kimmel Cancer Center
	19.	David	Loose	BLC
	20.	Jomol	Mathew	Dana-Farber
	21.	Patrick	McConnell	Duke University
	22.	Shannon	McWeeney	OHSU

	23.	Bob	Morrell	Wake Forest University
	24.	Joyce	Niland	City of Hope
	25.	Rachel	Nosowsky	Univ. of Michigan
	26.	George	Redmond	NCI/CTEP
	27.	Karen	Ryan	Booz Allen Hamilton
	28.	Pete	Schad	NCI DCCPS
	29.	John	Speakman	NCI CBIIT
	30.	Rhett	Sutphin	Northwestern
	31.	Susan	Varghese	Booz Allen Hamilton